Stakeholder Meeting August 30, 2011

Attendees:
Alan Clum – Mount Pleasant WaterWorks
Bruce Watt – Data Resources
Heather Beard – Richland County
Cheryl Johnson – Pace Analytical
Victoria Weathers – Ascend Performance Materials
Phil Thompson King – Chester Sewer District
Rudy Powell – Davis & Floyd
Crystal Rippy – SCDHEC BOW
Clint Elliot – GSWSA
Mahtab Gowan – SCDHEC LabCert
Tabatha Corley – SCDHEC Region 5
Sandra Flemming – SCDHEC EQC Labs
Melisa Ramey – Rogers & Callcott
Sam Avery – Rogers & Callcott
Thomsena Simmons – BP
Jami Savje – Shealy Environmental Services
Michael Woodrum – Shealy Environmental Services
Nydia Burdick – SCDHEC EQC Labs
Roger Brewer – SCDHEC EQC Labs
Mary Ann Fuller – SCDHEC BOW
Jeff Bailey – City of Inman
Chris Doll – SCDHEC BLWM
Rodney Wike – Duke Energy
Girish Sharma – Duke Energy
Cheryl Sommers – Commonwealth
Chris Cole – SCDHEC EQC Labs
Jamie Berry – SCDHEC LabCert
Susan Yates – SCDHEC Region
Larry McCord – Santee Cooper
Jeff Czarnecki – Greenville Water System
Alfred Baquiran – SCDHEC LabCert
Carol Smith – SCDHEC LabCert
Bennie Cockerel – SCDHEC LabCert
Leigh Plummer – SCDHEC Region 4
Jason Collins – Keowee Key Utility
Deborah Edwards – City of Rock Hill
Connie Gibson – SCDHEC LabCert
Melissa Robbins – City of Rock Hill
Susan Butts – SCDHEC LabCert

Updates: Carol Smith

This will be the last meeting with entire stakeholder group until the draft document is completed and is ready to review. The subcommittees and the Stakeholder representatives will be working on changes to address the comments received from our stakeholders.

Section H – Certification

This section outlines what laboratories have to do to apply for initial certification.

R.61-30 outlines the timeframes that would apply to additional and initial certification. R. 61-30 allows 90 days to complete the technical review of the application. The EFIS (Environmental Facility Information System) is the database where the review of applications is documented.

Comments:

What is section "QA/QC"?

This is the Quality Assurance/Quality Control section of the reg. The regulation is not finalized so instead of referencing the specific section by number or letter, it was labeled "QA/QC". Once the regulation is finalized it will document the specific section by reference number or letter.

Section H.(1)(b) -

REWORD SECTION

Bennie Cockerel suggested changing the wording to specify that the on-site will be set forth at Lab Cert's discretion. This language will be needed for additional parameter applications that may not need an on-site evaluation if it is a method they have been previously certified to perform.

Specify "during the technical review" instead of "after the technical review" – Susan Butts

Section H.(2) - No Comments

Section H.(3)(e) –

There was considerable discussion on what this section meant when discussing changes in the laboratory that must be reported to the Department. There was concern about what changes to personnel and equipment must be reported. It was discussed that the laboratory's Quality Assurance (QA) Plan must document the primary analysts and their responsibilities. Their qualifications and training would also be documented in the QA Plan. Equipment changes would be documented as an update to the SOP and may involve an initial demonstration of capability.

After much discussion it was decided that this section would be reworded and rearranged to clarify that the changes that would be communicated "in writing" are the following: laboratory name, ownership, laboratory director, location, and facilities.

What happens if the labs don't notify Lab Cert of these changes?
This may be grounds for decertification and will need to be addressed in the regulation.

Discussion also took place on when the Laboratory Certification Program would be notified about inoperable equipment and loss of their certification because they no longer had the equipment to perform the certified analysis. What is the timeframe for inoperable equipment that the analyst is subcontracting the analysis?

Why would we be decertified if the lab is not reporting or analyzing samples?

Labs could notify Lab Cert that they are not analyzing and state which lab that samples are contracted to. – Susan Butts

Reports specify which lab is analyzing the samples, so why do labs have to notify Lab Cert? – Larry McCord

What is the difference if you just decide not to analyze by a particular method versus not analyzing because the instrument is down? – Allan Clum

If you do not have equipment to properly analyze the samples by the certified method, the Office should be notified within 15 days of the equipment problem along with documenting what the lab will do to correct the problem. – CS

Maintenance on equipment should not have to be reported if the laboratory is planning on fixing it.

Section H.(3)(e) should be broken out and clarified what the laboratory must do for each change.

Everything should not be so specific that the smaller labs will have difficulty functioning. Do not get too specific.

Nothing is in the present regulation that states that the labs must notify the Office of any changes. – CS

This section will be reviewed and anyone with suggestions on the language should submit this to the Office. – CS

The notification should be submitted in writing and language added to state this. The Lab name, ownership, laboratory director, location, facilities will be included in Section 3.(e) – no comments

Every lab should have an inventory list for their equipment with serial numbers that can be provided to the Office. This should be part of the QA Plan. Changes in the inventory list can be documented.

It was decided to remove equipment from section 3.(e). The equipment list may be moved to another section of the regulation. – CS

Changes must be submitted in writing on letterhead. Changes must be official in order to make changes because it affects other departments in the Agency.

Section H.(3)(a) - What defines when analytical proficiency is not being maintained and what is the frequency (entire certification period)? – R Powell

Analytical proficiency would be as defined under the QA/QC Section of the regulation which usually refers to the method requirements. The (QA/QC) will be updated to reference the section for the QA/QC section of the regulation– CS

This must be specific and not subjective on Lab Certs part. – PR

Define “analytical proficiency”

This could be different things for different methods – CS

Revisit this section. – CS

This is vague because it’s only when Lab Cert reviews once every three years. When is the determination made?

During the audit and review of the data – CS

This could also be determined whenever data from the lab is reviewed or PT data. Other people may provide data that documents the analytical proficiency is not being maintained.

Other sections of the regulation specify this in more detail.

Note to make references to other sections in order to specify and clarify analytical proficiency. - CS

Many years down the road someone else may misinterpret this section differently and decertify for a vague reason.

Section H.(3)(c)
There will be no changes in the number of PTs required to obtain or maintain certification with this regulation change. – SB and CS

Section H(4)

Need alternate language to extend beyond three years if needed. – CS

Drinking Water laboratories are required to be evaluated every three years.

Section H.(5) - No comments

Section H.(6) - No comments

Section F. Definitions

"Analyte" should not be restricted to organic compounds. – R Powell

Suggestion: Change it to "the chemical substance, physical property, or organism being tested in a sample. Determine how it is being used in the final regulation before defining it.

Define "Taxonomy" - CS

"Parameter" – reexamine

The regulation needs to be searched to determine how each term is being used prior to the final definition. – CS

"Analyst" – No comments

"Certificate" – No comments

"Certification" – No comments

"Certifying Authority" – No comments

"COC" – No comments

"CFR" – No comments

"Decertification" – No comments

"DOC" – suggestion: add as defined by method.

This will be expanded and discussed in the regulation. – CS

"Department" – No comments

"EPA" – No comments

"Evaluation" – Suggestion: add equipment to this part. Suggestion: add what is being reviewed for personnel

Note: add equipment

Note: add additional language.
This does not need to be specific. It needs to be very general. It will document specifics in the regulation.

"Fees" – No comments

"Laboratory" – What does "may" mean in this context? This could mean that they don't have to do it in the laboratory and invite people to have a lab in the field or truck.

"LCO" – No comments

"Lab Director" – No comments

"Lab ID #" – No comments

"MDL" – No comments

"Office" – No comments

"Personnel" – No comments

"Preservation" – Suggestion: add the word physical

"PT Sample" – Suggestion: separate definition for proficiency testing or add acronym PT
Suggestion: use Performance Efficiency Sample PES

"Qualifier" – Suggestion submitted by Rudy Powell, Suggestion: use Rudy's definition but remove the word "code". Suggestion: "Quality problems"…qualifier does not always mean problems. Use issues instead of quality problems. All agreed to use slightly altered suggested language.

"Quality Assurance" – No comments

"Quality Control" – No comments

"Reciprocity" – No comments

"RL" (Reporting Limit) – Suggestion: add aka PQL (Practical Quantitation Limit), Suggestion: if we start putting aka's do we need to include all, Suggestion: the definitions should be defined and labeled as listed in this regulation. Suggestion: we need to use terms that are used by the Department

"Sample batch" – Suggestion: add "required quality control", Do we need this defined? We will need to research this – CS, maybe just define batch. There is also preparation batch and analytical batch.

"Shall" – No comments

"Should" – the regulation will be updated to only use "shall" and "should" within the document.

"Support equipment" – No comments

Comments from Group on Regulation:

Requirements for Laboratory Director – Heather Beard
"Shall have a bachelor degree" – leaves out a large group of people
Several comments on changing the language of the waiver or specifying automatic inclusion of people who do not meet this requirement. (Such as field parameter labs) Language would state

that laboratories that just perform pH, DO, residual chlorine and temperature are excluded from this requirement. Or change the waiver statement to include these people.
Broaden academic requirement to include other types of degrees.

Suggestion: academic, technical, and professional experience – Heather Beard
Agency should not restrict who a company hires. – Jason
If requiring a BS it should be in a related discipline. The waiver is to cover the people who do not meet the educational requirements. – Larry McCord

Suggestion for alternate language is welcomed and can be submitted to Personnel Qualifications subcommittee.
Suggestion: add "minimum requirement" not to exclude people who have more education.

Subcommittee will continue work on this section.

Stakeholder Submitted Comments:

Discussed the "Comments" submitted by our stakeholders to Draft Document for Regulation 61-81.

C. Scope: Incorporated "and/or measurements". Legal Office is being consulted concerning the scope so as to not exclude other programs, suggestion to define "environmental quality evaluations/assessments".

E. Parameters Requiring Certification: add "Management" to Act. This is also being discussed with the legal office.

F. Definitions: discussed earlier in the day, grammatical error suggestions.

H. Certification: Look at this further to take suggestion into consideration.

Certification Criteria: I.1.a & b are accurate – No comments. Person who made the original comment will be consulted for clarification about the comment.

Laboratory Equipment: I.3.c.ix – quarterly would be the preferred minimum, should the deleted language be reincorporated? Volumetric dispensing device will be discussed in the QA/QC subcommittee,
I.3.e – changed language to specify the timeframe of once a year. Will reevaluate to clarify the intent of the requirement.

Personnel Qualifications: discussed earlier in the day. This will worked on by the subcommittee.

Standard Operating Procedures: I.6 – group didn't have any issue with the elements.

Sample Collection, Preservation, and Handling Procedures:

Thermal preservation – don't you have to be certified for temperature to show a downward trend? Sample collector would not be reporting the temperature of the sample. This will have to be discussed further.

Data Reporting and Laboratory Test Reports:

Does the comment to section L. (1)(c) refer to pretreatment? Check with the commenter for clarification.

L. (1)(ix) – the intent of this section was for when there is a report provided to a client it must be signed by the laboratory director. Not sure of the meaning of this comment?

Loss of Certification: timeframe that the decertified lab to provide a name of the certified lab they are using – suggestion: 24 hours, suggestion: why does this have to be provided to the department,

Recertification: Clarify this statement to differentiate between total laboratory decertification and parameter decertification.

General Comments:

Concern that the word “compliance sampling” and “compliance testing” would limit this requirement because there are other types of required sampling. – Crystal Rippy

Rejecting samples – not all program areas have the same type of reporting requirements and specifications. The contract labs cannot provide the department with electronic deliverables, it must come from the client. The commercial labs want to run the samples with flags, Dept. doesn’t want data for samples that are out of holding times, unpreserved, etc. Commercial labs - customer service should be emphasized along with client communication to ensure that there are not problems with sample preservation or holding times. NC requires that if there is a preservation or sample out of hold time issue it must be reported to NC Reg. Agency. Some of the larger commercial laboratories supported this requirement.

Section F and Q: why were these sections removed? These are being reworded and put in a different section of the regulation.

Conclusion

Subcommittees are to regroup and address the comments related to their sections.

If anyone has additional comments submit them as soon as possible. Suggested language would be very helpful. Additional draft documents will be put out for review. Forward any comments to the appropriate subcommittee or to Carol Smith.

Interested people are welcome to join any of the subcommittees. A list of the subcommittees is on the Website.

Thanks to all for their participation in this process - Sandra Flemming